REMARKS

Status of the Claims

Claims 1, 3 – 14, 16 – 18, 22 – 24, 27 – 33 are pending. Claims 2, 15, 19 – 21, and 34 are canceled. Claims 25 and 26 have been withdrawn from consideration.

Claim Amendments

The claim amendments are made without prejudice, and without disclaimer of the canceled and/or modified subject matter. Indeed, "[t]he language in the … claims may not capture every nuance of the invention or describe with complete precision the range of its novelty."[1] Thus, "[t]he scope of [the present claims] is not limited to [their] literal terms but instead embraces all equivalents to the claims described."[2]

The amendment to claim 1 does not add new matter, because the amendment is supported on page 11, lines 1 – 5 of the specification.

The amendment to claim 29 does not add new matter. The phrase "water-soluble or lipophilic polymers" has been amended to "water-soluble or lipophilic additives." This amendment ensures proper antecedent basis, and finds support on page 1, line 9 of the specification.

The cancelation of claim 34 does not add new matter, because the cancelation does not affect the scope of any pending claims.

Claim Rejections

I. The Office action rejects claims 1, 3 – 14, 16 – 18, and 22 – 34 under 35 U.S.C §112, first paragraph

The Office action rejects claims 1, 3 – 14, 16 – 18, and 22 – 34 under 35 U.S.C

[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731, 122 S.Ct. 1831, 1837 (2002).
[2] *Festo*, 535 U.S. at 731, 122 S.Ct. at 1837.

§112, first paragraph, for two reasons.

First, the Office action alleges that the phrase "based on the weight of the oral dosage form" in the limitation specifying the amount of active ingredient to be released within the first hour is not supported in the specification. Applicants respectfully submit that the above-mentioned phrase is inherently disclosed in the specification as filed, because the results of the release test (for example, as listed in Table 2) were obtained in accordance with the USP XXIV Paddle Test. According to that test, a tablet, i.e., a dosage form, is positioned in the paddle apparatus and release of the active ingredient is monitored over the time. The amount of released active ingredient in percent determined according to this method is inevitably based on the weight of the total weight of the dosage form. Applicants have amended claim 1 to state, wherein said delayed release is defined as limiting the amount of active ingredient released in the first hour to 25.3%, measured according to USP XXIV paddle method.

Second, the Office action alleges that the phrase "pre-formulated mixture" in claim 1, is not supported in the specification. Applicants respectfully submit that this phrase is supported on page 1, lines 7 – 8 of the specification.

II. The Office action rejects claims 29 and 30 under 35 U.S.C §112, second paragraph.

The Office action rejects claims 29 and 30 as being indefinite. The rejection of claim 29 should be overcome by the amendment to claim 29, whereby the phrase "water-soluble or lipophilic polymers" has been changed to "water-soluble or lipophilic additives."

With respect to claim 30, the Office action alleges that the additives listed are not lipophilic additives. Applicants respectfully disagree. The enclosed Declaration of Dr. Kolter explains, the additives such as fatty alcohols, glycerides, waxes, etc. are indeed lipophilic additives. The Declaration adds, that a person having ordinary skill in the art knows said additives cited in the present application are insoluble in water, but are readily soluble in hydrocarbons, which is a typical behavior of lipophilic substances. Applicants also respectfully submit the enclosed copies of Fiedler's Encyclopedia of

Excipients to exemplify that both stearic acid and stearyl alcohol are classified as being insoluble in water, but soluble in alcohols and in fat solvents. Applicants respectfully submit that the Dr Kolter's Declaration, and Fiedler's Encyclopedia of Excipients demonstrate that the additives listed in claim 30 are not lipophobic, but are instead, lipophilic. The relevant portions of Fiedler's Encyclopedia of Excipients are represented below for the Examiner's convenience:

Stearic acid

**Properties** White leaflets or white powder, with fat-like odor, insoluble in water, soluble in alcohols and fat solvents.

Stearyl alcohol

**Properties** Colorless leaflets, insoluble in water, soluble in alcohol and fat solvents. Mp 59°, d 0.8124, bp 210.5°.

For the sake of completeness applicants respectfully note that claim 30 finds support in original claim 8, and on page 7, lines 39 – 40 of the specification.

III. The Office action rejects claims 1, 4, 7 – 12, 14, 16 – 18, 22, 24, and 31 – 33 under 35 U.S.C §102(b) as anticipated by US 4,837,032 to Ortega (hereinafter, "Ortega").

Applicants respectfully submit that Ortega does not disclose a pre-formulated mixture of PVAc and PVP. The enclosed Declaration of Dr. Kolter makes reference to page 3, lines 17 – 21 of the specification to explain that a pre-formulated mixture, according to the present invention, is an intimate mixture of constituents, obtainable, for example, as described in US patent No. 5,490,990, by spray-drying a dispersion containing two polymeric components. Such pre-formulated mixtures cannot be separated mechanically, and when examined under a light microscope, the constituents cannot be distinguished as different components. Dr. Kolter explains that Ortega does not disclose the polyvinyl acetate and all of the polyvinyl pyrrolidone are pre-formulated to give an intimate mixture wherein the two components cannot be separated mechanically. Mere mixing of components does not lead to a pre-formulated mixture.

Dependent claim 33 is directed to an oral dosage form as claimed in claim 1, wherein the oral dosage form has a hardness of greater than 200 N. At column 4, lines 10 – 13, Ortega states, the resulting mixture may then be compressed using a standard rotary

tablet press. Preferably the tablets are compressed to a hardness of 4 to 10 kg (Erweka Tester). As explained in Dr. Kolter's Declaration, a hardness of 4 to 10 kg (Erweka Tester) is equivalent to a tablet hardness of only 40 to 100 Newton. Thus, Ortega does not describe an oral dosage form as claimed in claim 33, having a hardness of greater than 200 N.

Applicants respectfully request reconsideration of the present rejection, in light of these comments and the enclosed declaration.

IV. The Office action rejects claims 1, 3 – 14, 16 – 18, 22 – 24, and 27 – 33 under 35 U.S.C §103(a) over US 6,066,334 as a translation of DE 197 09 663 to Kolter et al. (hereinafter, "Kolter") and Ortega.

The Office action acknowledges that Kolter does not teach the claimed release rate, but alleges that adjusting the release profile of Kolter is no more than manipulating a result effective parameter in a predictable fashion. In the enclosed declaration, Dr. Kolter discusses the proposed combination of Kolter and Ortega.

As discussed above, dependent claim 33 is directed to an oral dosage form as claimed in claim 1, wherein the oral dosage form has a hardness of greater than 200 N. At column 4, lines 10 – 13, Ortega states, the resulting mixture may then be compressed using a standard rotary tablet press. Preferably the tablets are compressed to a hardness of 4 to 10 kg (Erweka Tester). As explained in Dr. Kolter's Declaration, a hardness of 4 to 10 kg (Erweka Tester) is equivalent to a tablet hardness of only 40 to 100 Newton. Thus, a person of ordinary skill in the art had no apparent reason to expect the proposed combination/modification to result in an oral dosage form as claimed in claim 33, having a hardness of greater than 200 N.

Applicants respectfully request reconsideration of the present rejection, in light of these comments and the enclosed declaration.

V. The Office action rejects claims 1, 3 – 14, 16 – 18, 22 – 24, and 27 – 34 under 35 U.S.C §103(a) over Kolter, Ortega, and US 4,816,259 to Matthews et al. (hereinafter, "Matthews").

The Office action acknowledges that Kolter and Ortega do not teach a coating, but alleges that it would have been *prima facie* obvious for a skilled artisan to coat the tablets of Kolter and Ortega with PVP/PVAc according to Matthews. Applicants respectfully note that claim 34 is canceled.

Matthews does not teach pre-formulated mixtures of PVAc/PVP to be used for coatings. Matthews does not teach a combination of PVAc/PVP at all. Matthews merely recites a list of polymers for use in coating solutions, PVAc and PVP being among the polymers listed. Applicants respectfully submit that Matthews provides no apparent reason to combine PVAc and PVP, to admix PVAc and PVP, let alone to form a pre-formulated mixture PVAc and PVP.

Furthermore, with respect to dependent claim 33, a person of ordinary skill in the art had no apparent reason to expect the proposed combination/modification to result in an oral dosage form as claimed in claim 33, having a hardness of greater than 200 N.

Applicants respectfully request reconsideration of the present rejection, in light of these comments and the enclosed declaration.

Petition for Extension of Time

Applicants respectfully request that a three-month extension of time be granted in this case. The respective $1110.00 fee is paid by credit card.

Fee Authorization

Please charge any shortage in fees due in connection with the filing of this paper, including any shortage in Extension of Time fees, to Deposit Account 14.1437. Please credit any excess fees to such account.

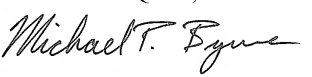
Conclusion

The present application is in condition for allowance, and applicants respectfully request favorable action. In order to facilitate the resolution of any questions, the Examiner is welcome to contact the undersigned by phone.

NOVAK DRUCE + QUIGG, LLP
1300 Eye St. N.W.
Suite 1000 West
Washington, D.C. 20005

Phone: (202) 659-0100
Fax: (202) 659-0105

Respectfully submitted,
NOVAK DRUCE + QUIGG, LLP



Michael P. Byrne
Registration No. 54,015

Enclosures (2):

- Declaration of Dr. Karl Kolter, and
- Fiedler Encyclopedia of Excipients, Vol. 2 L-Z, OIM crossmedia GmbH, München, Germany, (2007), pages 1368, and 1371.